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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Our Ref: 1887-181 MIS/bh

Prior Application: 08/307,621

Examiner: L. Leary

Art Unit: 1211

April 10, 1997

The Commissioner of Patents and Trademarks,
Box FWC,
Washington, D.C. 20231,
U.S.A.

Dear Sir:

PRELIMINARY REMARKS

In the parent application, Petition was submitted pursuant to 37 C.F.R. 1.313(b) (5) to withdraw this application from issue for the purpose of consideration of an Information Disclosure Statement under 37 C.F.R. 1.97 in this file wrapper continuation (FWC).

This FWC is accompanied by a PTO-1449 listing the Dissertation Thesis and Abstract thereof by one of the inventors and enclosing a copy thereof. It is not believed that this reference is relevant for the following reasons:

In considering this prior art, it is important to bear in mind the nature of the invention which is sought to be protected. The invention lies in the treatment of the occurrence of hypertrophic scar in humans using a non-toxic transglutaminase inhibitor. The formation of such scar tissue is itself an unpredictable event and is now known to arise from an accumulation of collagen type III in relation to type I.

The work done by the inventor on which the patent application is based was on human patients and it is believed that it was not predictable that the treatment described and claimed in the patent application would be successful in humans until such trials were conducted.

The Dolynchuk Thesis is a study of the mechanism of wound healing, with hypotheses being drawn from a prior study of the literature. It is stated on page 51:

"Review of the literature led to the hypothesis that glycoproteins other than collagen may be formed in wounded skin and that collagen-glycoprotein interactions may occur during wound healing."

"A second hypothesis was that transglutaminase may be involved in wound healing through glycoprotein cross-linking. This hypothesis arose from the findings of other workers which suggested that a role for transglutaminase in wound healing might involve isopeptide bond formation between fibrin and collagen, and from the finding in the present work (Section III, 1) that the [3^H] glucose-labelled material synthesized by wound tissue is difficult to solubilize."

The final conclusion of the thesis (page 109) is:

"It is hypothesized that isopeptide cross-linking of the fucoprotein may be necessary for growth of collagen fibres in the wound tissue matrix. Therefore, use of transglutaminase inhibitors may be of therapeutic consideration in disorders of fibrous proliferation such as hypertrophic scar and other fibrocontractive disease processes."

This same paragraph is contained in the Thesis Abstract. The conclusion is a speculation as to what might be, based on observation in rats.

This paragraph does not, it is submitted, disclose or suggest the invention which is claimed. Having regard to the study conducted, it is a surprising result that hypertrophic scar tissue in humans may be treated and the results which have been obtained achieved.

These comments are submitted at this time to assist the Examiner in consideration of the relevance of the newly-cited art to the claimed subject matter.



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